

COVID-19 Update: Grand Rounds

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AltaMed

QUALITY CARE WITHOUT EXCEPTION™

Main Points of Discussion

- **Vaccines for Immune Suppressed Individuals**
- **Upcoming Booster Recommendations**
- **Testing for Unvaccinated Staff**
- **Vaccine Requirements at AltaMed**
- **Vaccine Recommendations for Pregnant and Breastfeeding Women**
- **Update to Safe Environment: Gatherings at Work**
- **Update on Treatment with Monoclonal Ab for underinsured**
- **Questions**

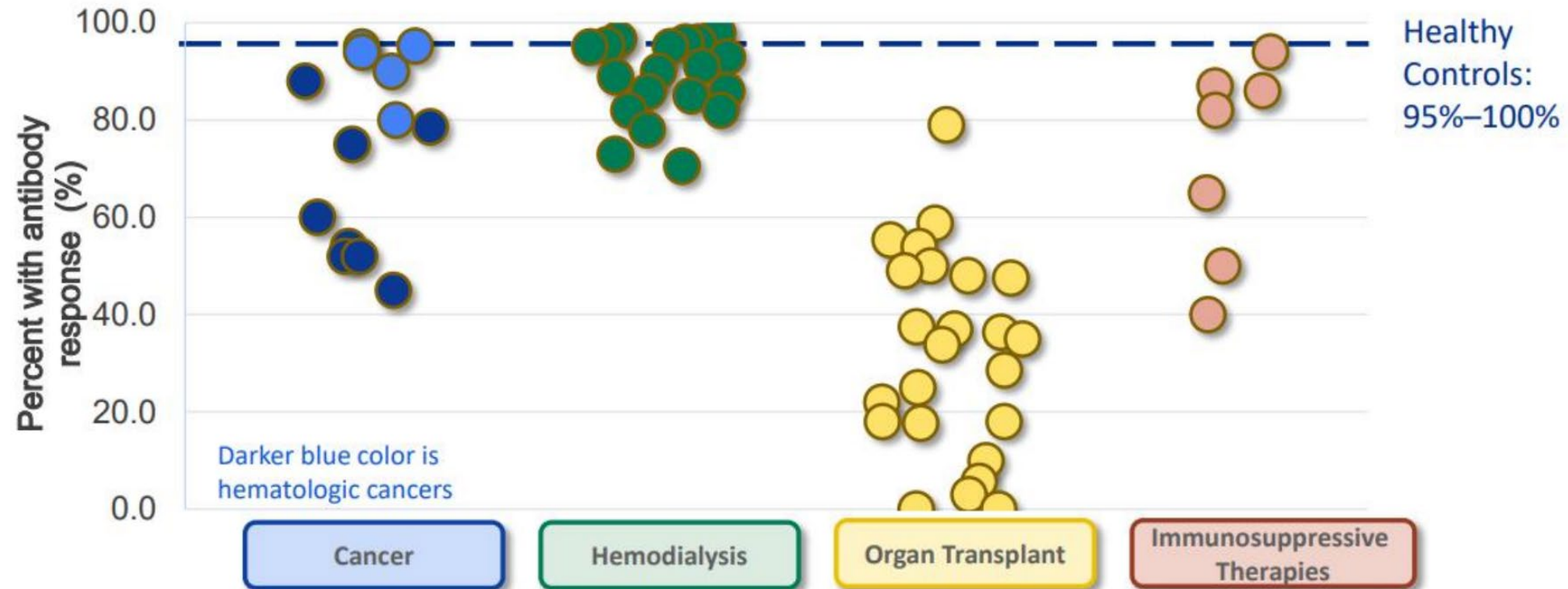


Immunocompromised People and Vaccine Breakthrough Infection

- More likely to have breakthrough infection
 - 40-44% of hospitalized breakthrough cases are immunocompromised people in US study¹⁻²
- Lower vaccine effectiveness
 - 59--72% VE among immunocompromised people vs. 90--94% among non-immunocompromised people after 2nd dose^{1, 3-5}



Percent of subjects with antibody response after two mRNA COVID-19 vaccine doses by immunocompromising condition and study (n=63)



- Studies that compared response after 1st and 2nd dose demonstrated less robust response after dose 1
- Antibody measurement and threshold levels vary by study protocol

Benefits and Harms: Summary of the Available Evidence

Benefits:

- Emerging experimental and observational data in adults suggest that an additional mRNA COVID-19 vaccine dose in immunocompromised people enhances antibody response and increases the proportion who respond to COVID-19 vaccine
- No efficacy or effectiveness studies of COVID-19 prevention following a 3rd dose

Harms:

- In small studies of an additional dose of mRNA vaccine
 - No serious adverse events were observed
 - Reactogenicity of the 3rd dose of mRNA vaccine was similar to prior doses
- mRNA COVID-19 vaccines are associated with rare but serious adverse events, including anaphylaxis as well as myocarditis and pericarditis in young adults. The impact of immunocompromising conditions on these rare events is unknown.
- There are no safety studies of an additional mRNA dose in immunocompromised adolescents

1. Individuals must be fully vaccinated for COVID-19 and have completed their vaccine series 28 days or more from their last COVID-19 vaccine.
2. Fully vaccinated is defined as prior 2 doses of Pfizer or Moderna vaccines. At this time there is not an approval for booster vaccines for Johnson and Johnson vaccines.
3. Fully vaccinated individuals with the following conditions may start scheduling appointments for booster doses of the COVID-19 vaccine to begin on Monday, August 16th, 2021.

History of Solid Organ Transplant

History of Bone Marrow or Stem Cell Transplant

Current Cancer or on Chemotherapy

HIV

Chronic Steroid Use for 1 Month or More

Use of Immune Modulating Therapies Such as Rituximab

Kidney Disease Requiring Dialysis

Presence of Cirrhosis

Inherited or Acquired Immune Deficiency Syndromes [link](#)

4. The booster vaccine must be of the same brand as the prior complete series. For example: fully vaccinated with Moderna must then receive a 3rd dose of the Moderna vaccine.
5. COVID-19 vaccine may be given with other non-COVID vaccines.

Conditions and Treatments

Include:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., $\geq 20\text{mg}$ prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.



Timing, testing

- Until additional data are available, the additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series, based on expert opinion.
- Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be completed at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine.
- Serologic testing or cellular immune testing is **not recommended at this time**.

Counseling on Continuing Prevention Measures

- People who are immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines and the need to continue to follow current prevention measures
 - wearing a mask
 - staying 6 ft apart from others they don't live with
 - avoiding crowds and poorly ventilated indoor spaces
- Close contacts of immunocompromised people should also be strongly encouraged to be vaccinated against COVID-19 to protect these people.

Process for Scheduling 3rd Dose

- HIV/AIDS patients can be directly scheduled
- Other patients are being scheduled with providers
- Providers counsel patients
- If need 3rd dose then have support staff schedule patient for 3rd dose
- Front office team is working on labeling the third dose appointment, if you have trouble scheduling escalate to manager
- Attestation form should be signed by patients prior to getting dose
 - English and Spanish versions
- Updated EUA for patients and providers for Moderna and Pfizer, make sure that packet is updated, if not take it apart and put in the correct EUA
- Will be documented as a 3rd dose

Upcoming Boosters

- **Anticipated recommendation that people that are 8 mo or more out from mRNA vaccines should get a 3rd dose**
- **This group includes Healthcare workers, 1st Responders and Nursing Home patients.**
- **Key, subtract 8 from Month. September (9-8=1), People fully vaccinated January or Before should get 3rd dose.**
- **Will likely come out mid-September.**
- **Johnson and Johnson still waiting, we are held to EUA standards**

Testing Undervaccinated Staff

- **Starting August 18th, those that are unvaccinated or not fully vaccinated will need to be tested twice per week**
- **We will be using COVID antigen testing,**
- **Testing will be done at worksite**
- **EUA authorized test so need to provide EUA for staff that are being tested.**
- **Expiration date may show they are already expired, FDA extended the expiration date so they are still good, Supply Chain is monitoring this closely**
- **Vaccines will be made available onsite where vaccines are being stored for employee COVID-19 vaccine**

Vaccine Requirements for Staff

- **All AltaMed Staff will need to be fully vaccinated by Sept 30th 2021**
- **Policy getting approved by the board but we are following Governor Newsom's Health Officer Order from July 26th, 2021 and August 5th, 2021.**
- **Need to have 2 doses of mRNA or 1 dose of Janssen vaccine before Sept 30th, 2021.**
- **Exemption Attestation sent out to all undervaccinated staff**
- **Medical Exemption will be considered for absolute contraindications for the vaccine**
- **Those with Anaphylactic or allergic reaction to mRNA vaccine, should be considered for Janssen vaccine**
- **Other medical reasons for exemption will be reviewed by Committee.**

Teammate Section: Complete the following information

Name (last, first) _____ Employee ID: _____

Work Email Address: _____ Best Phone Number: _____

After you and your provider complete this form, scan it and email to Employee Health (employeehealth@altamed.org)

The form will be kept as part of your confidential employee health record.

Clinician Section: A licensed physician, P.A., CNM or NP must complete and sign this section. (Forms completed by the employee will not be accepted)

Clinician Instructions: By completing this form, you certify that different methods of vaccinating against COVID-19 have been considered are that the following medical contraindication precludes any/all vaccinations for COVID-19. Guidance for medical exemption for COVID-19 vaccinations can be obtained from the Advisory Committee on Immunization Practices (ACIP) available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

If a pregnancy exception is requested, this signed form from the provider is not necessarily an endorsement of exemption. The provider just needs to confirm pregnancy and provide Estimated Date of Confinement (return to work date) below.

The following are **NOT** considered contraindications COVID-19 vaccination:

- *Local injection site reactions after (days to weeks) previous COVID-19 vaccines (erythema, induration, pruritus, lymphadenopathy, vomiting, diarrhea, myalgia, arthralgia)
- *Previous COVID-19 infection
- * Vasovagal reaction after receiving a dose of any vaccine
- * Being an immunocompromised individual or receiving immunosuppressive medications
- * Autoimmune conditions, including Gillian-Barre Syndrome
- * Allergic reactions to anything not contained in the COVID-19 vaccines, including injectable therapies, food, pets, venom, environmental allergens, oral medication, latex, etc. Please note the COVID vaccines do not contain egg or gelatin.
- * Immunosuppressed person in the healthcare worker's household
- * Alpha-gal Syndrome
- * Family member or household member who falls into a medically exempt category
- * Breastfeeding intention to become pregnant or undergoing infertility treatment

Please indicate medically indicated contraindication below:

- Severe allergic reaction (anaphylaxis) after previous dose of or to a component of the COVID-19 Vaccine. Including Polyethylene Glycol (PEG) (Please describe response in detail below and contraindication to alternatives, such as the Johnson & Johnson vaccine, which does not contain PEG)
- Immediate allergic reaction to a previous doses or known (diagnosed) allergy to a component of the vaccine (Please describe response in detail below and contraindication to alternative vaccines)
- Other medical circumstances preventing vaccination with any available COVID-19 vaccine (Be specific and describe in detail below) Please note that this will be reviewed by the medical exemption committee. Submission of a signed form does not guarantee and exemption will be granted.
- Pregnancy (Note: [The American College of Obstetrician and Gynecologists](#), [the Society for Maternal-Fetal Medicine](#) and the [American Society for Reproductive Medicine](#) all strongly support COVID-19 vaccine before and during pregnancy and while breastfeeding.) Pregnancy is not a medical contraindication. However, a time deferment to the COVID-19 vaccine policy will be granted during pregnancy. Employees will need to receive vaccination when they return back to work. Return to work date: _____

COVID Vaccine in Pregnant and Breastfeeding Individuals

- No safety signals from updated data in pregnant and breastfeeding people
- Antibodies protect baby from COVID-19 similar to Flu vaccine and Tdap vaccine
- CDC, FDA, ACOG and Society of MFM endorse vaccine for this population
- Recommend mRNA vaccine (Moderna or Pfizer) due to risk of thrombosis in Female <50 population

Table 2. V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant individuals

Pregnancy Complications [†]	Background Rate	V-safe Pregnancy Registry Overall
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%
Neonatal Outcomes*	Background Rate	V-safe Pregnancy Registry Overall
Preterm birth	8-15%	9.4%
Congenital anomalies	3%	2.2%
Small for gestational age	3.5%	3.2%
Neonatal death	0.38%	0%

*Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. CDC v-safe COVID-19 Pregnancy Registry Team [published online April 21, 2021]. *N Engl J Med*. DOI: 10.1056/NEJMoa2104983. Available at: <https://www.nejm.org/doi/10.1056/NEJMoa2104983>.

Safe Environment Update: Gathering at Work

Sherrill Brown, MD
Director, Infection Prevention



Clinical Sites including PACE (Non Dental)

Precautions	Employees when not patient facing	Employees <6ft from others or while interacting with patients	Staff Caring for Patients with Transmissible Disease Risk**	Staff Caring for Visitors and Patients with Low Risk for Transmissible Disease***	Visitors and Patients
Screening	Yes	Yes	Yes	Yes	Yes
PPE	Minimum Surgical Face Mask at all times (Respirator Made Available) ^{tt}	Minimum Surgical Face Mask at all times (Respirator Made Available), Face Shield if not separated by plexi-glass partition	Transmission Based Precautions + minimum Surgical Face Mask ^{tt} + Face Shield	Surgical Face Mask or Respirator + Face Shield ^{tt}	Clinic provided Surgical Face Mask
Distancing	Yes 6ft	Yes 6 ft if possible	As exam dictates but attempt to remain 6ft during most of the visit	As exam dictates but attempt to remain 6ft during most of the visit	Yes* 6 ft
Frequent Hand Hygiene	Yes	Yes	Yes	Yes	Yes
Cleaning	Before and After Shift Work Station, Before and After Shared Table Use	Before and After Shift Work Station, Before and After Shared Table Use	HEPA filter per Transmission Based Precautions, Cleaning Based on Transmission Based Precautions	Routine Room Turnover	Routine Cleaning Lobby, Disinfect Shared Tables before and after Use

*Physical Distancing in lobby based on updated CDPH and CDC recommendations for ambulatory healthcare facilities

^{tt} Staff must be fit tested and trained on usage prior to using an approved Respirator. Dispose of disposable respirator after each shift. Clean face shield between patients and store as instructed. Dispose of gowns and gloves in between patients.

**Transmissible Disease Risk: Those that are determined to have risk factors for COVID-19 or other contagious infectious disease through entry or check in screening.

***Low Risk for Transmissible Disease: Not determined to have risk factors for COVID-19 or other contagious infectious disease through entry or check in screening.

Clinical Areas Dental

Precautions	Employees when not patient facing	Employees <6ft from others or while interacting with patients	Staff Caring for Patients with Transmissible Disease Risk**	Staff Caring for Visitors and Patients with Low Risk for Transmissible Disease***	Visitors and Patients
Screening	Yes	Yes	Yes	Yes	Yes
PPE	Minimum Surgical Face Mask at all times (Respirator ^{tt} made available)	Minimum Surgical Face Mask at all times (Respirator Made Available), Eye Protection if not separated by plexi-glass partition	Face Shield, Respirator, Gown, Gloves ^{tt}	Face Shield, Respirator, Gown, Gloves ^{tt}	Clinic provided Surgical Face Mask
Distancing	Yes 6 ft	Yes 6 ft if possible	As Exam Dictates	As Exam Dictates	Yes* 6 ft
Frequent Hand Hygiene	Yes	Yes	Yes	Yes	Yes
Cleaning	Before and After Shift Work Station, Before and After Shared Table Use	Before and After Shift Work Station, Before and After Shared Table Use	HEPA filtration, Cleaning Based on Transmission Based Precautions, Extra Oral Vacuum, Rubber Dam for Procedures	HEPA filtration, Extra Oral Vacuum, Rubber Dam for Procedures	Routine Cleaning Lobby

*Physical Distancing in lobby based on updated CDPH and CDC recommendations for ambulatory healthcare facilities

^{tt} Staff must be fit tested and trained on usage prior to using an approved Respirator. Dispose of disposable respirator after each shift. Clean face shield between patients and store as instructed. Dispose of gowns and gloves in between patients.

**Transmissible Disease Risk: Those that are determined to have risk factors for COVID-19 or other contagious infectious disease through entry or check in screening.

***Low Risk for Transmissible Disease: Not determined to have risk factors for COVID-19 or other contagious infectious disease through entry or check in screening.

Administrative locations (non-patient facing)

Precautions	Employed, Contracted or Volunteer Staff	Visitors	Meetings Indoors	Meetings Outdoors
Screening	Yes	Yes	Yes	Yes
PPE	Surgical Face Mask but <u>Respirator^{tt}</u> made available.	Surgical Face Mask but <u>Respirator^{tt}</u> made available.	Surgical Face Mask with <u>Respirators^{tt}</u> made available, Must wear mask when not actively taking a bite or taking a drink.	Staff Members Mask with <u>Respirators^{tt}</u> made available when not Eating or Drinking
Distancing	Yes <u>6 ft</u>	Yes 6ft	Yes <u>6 ft</u>	Yes <u>6 ft</u>
Hand Hygiene	Yes	YEs	Yes	Yes
Cleaning	Before and After Shared Equipment and Shared Work Stations	Before and After Shared Equipment and Shared Work Stations	Single serve and individually wrapped items or served by an attendant that is masked. Disinfect Tables before and after Use.	Single serve and individually wrapped items or served by an attendant that is masked. Disinfect Tables before and after Use.

^{tt} Those wearing respirators should be fit tested. Dispose of disposable respirator after each shift.

Indoor Meetings/Gatherings

1. All participants must be screened for COVID exposure risk or symptoms prior to meeting.
2. All participants wear masks unless actively taking a sip or bite of food.
3. All participants sit 6 feet apart.
4. All food or beverages being served must be in single serve and individually packaged servings or be served by an attendant who is masked.
5. Hand hygiene station should be made available near beverage/food area and easily accessible by all meeting participants.
6. Disinfect Tables Before and After Use.

Outdoor Meetings/Gatherings

1. All participants must be screened for COVID exposure risk or symptoms prior to meeting.
2. All participants wear masks unless actively eating or drinking.
3. All participants should sit a minimum 3 feet apart.
4. All food or beverages being served must be in single serve and individually packaged servings or be served by an attendant who is masked.
5. Hand hygiene station should be made available near beverage/food area and easily accessible by all meeting participants.
6. Disinfect Tables Before and After Use.

Monoclonal Antibody Treatment for COVID-19 High Risk Patients

July 6th, 2021

Ursula Baffigo MD MPH Medical Director, Medical Management



Inclusion Criteria

- Inclusion criteria:
 - 12 or older age group
 - Weigh at least 40 kg
 - Positive COVID-19
 - Within 10 days of symptom onset
 - Meets **high risk criteria**

High Risk Conditions

- Obesity or being overweight (BMI >25 or if age 12-17, have BMI ≥85th percentile for their age and gender)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

.MONOCLONALABTX

MONOCLONAL ANTIBODY INFUSION ORDER FOR COVID-19 POSITIVE PATIENTS

INSTRUCTIONS: REQUIRED STEPS

* Print & fill out manually OR download & fill out electronically:

* Use Adobe Acrobat  and select 

* [Instructions for changing default program for PDFs to Acrobat](#)

PROVIDER: Place Epic order "Referral to Home Health > IV Infusion" + mark order as **Urgent**

Under order comments enter "MONOCLONAL ANTIBODY THERAPY"

Fill out the attached **Infusion Order Form**

* *Team member may complete form based on documentation in Epic, but **PROVIDER must sign***

Completed AND signed form must be RETURNED to AltaMed Centralized Referral Team for urgent processing:

Provider or Clinic CGC's can return form via
Email: DL_Referral_Coordinators@altamed.org
or **Fax:** (323) 596-2166

Send message to [Justin Maldonado](#) on WebEx Teams to confirm that ORDER is placed & form emailed/faxed

MONOCLONAL ANTIBODY INFUSION ORDER FOR COVID-19 POSITIVE PATIENTS (Adult and Pediatric Patients)

The patient or his/her guardian have provided their informed consent for the administration of **REGEN-COV (Casirivimab + Imdevimab)**

I have notified the patient that this therapy is approved for emergency use by the FDA.

Home Infusion Provider Order Form for Casirivimab + Imdevimab

Patient Name: _____ DOB: _____

Patient Phone #: _____

Allergies: _____

Patient's Height (in) or (cm): _____ Patient's Weight (lb) or (kg): _____

Is Patient Pregnant? Yes No

Date of First COVID related Symptom Onset: _____

COVID Positive test Date: _____

DIAGNOSIS:

Covid-19 Infection (U07.1)

Other: _____

Administer Monoclonal Antibody Drug Therapy within 10 days of symptom onset.

Patient Eligibility Exclusion Criteria: (Patients meeting any of the following criteria are **NOT ELIGIBLE** for either therapy)

- who are hospitalized due to COVID-19
- who require oxygen therapy due to COVID-19
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity

By signing this order, physician verifies that none of the above criteria apply.

Inclusion Criteria:

- Patient is 12 years of age or older weighting at least 40 kg (88.2lbs)

At least one of the following criteria must be met to qualify for therapy (Select all that apply):

- Older age** (for example, age ≥65 years of age)
- Obesity or being overweight** (for example, BMI >25 kg/m², or if **age 12-17**, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)

Questions?

- CDC COCA Calls
- IDSA/Clinician Calls Every Other Week
- SHEA Weekly TownHall



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